

APPLICANT(S): GLUKHOVSKY, Arkady  
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### **REMARKS**

The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Applicant asserts that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

### **Status of Claims**

Claims **11-46** are pending in the application, of which claims **21-34** are withdrawn from consideration.

Claims **11-20** have been rejected.

Claims **35-46** have been newly added in this submission. Applicant respectfully asserts that the newly added claims add no new matter.

### **Personal Interview**

Applicant wishes to thank Examiner Smith for granting an interview with Applicant's representative, Guy Yonay, Reg. No. 52,388. Although no agreement was reached, the interview was productive in explaining the non-obviousness of the pending claims. The remarks set forth herein reflect the comments presented during the interview.

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## CLAIM REJECTIONS

### 35 U.S.C. § 103 Rejections

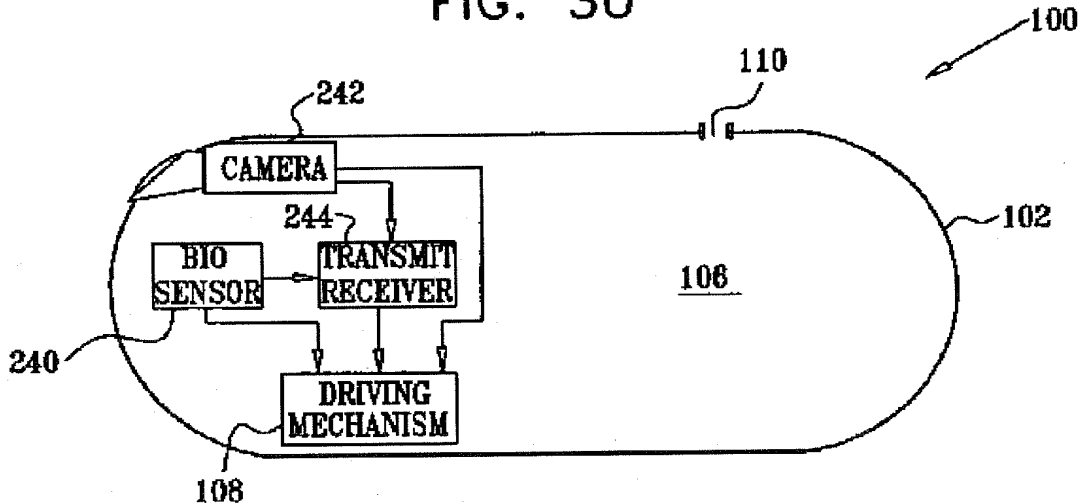
In the Office Action, the Examiner rejected claims 11-20 under 35 U.S.C. § 103(a), as being obvious over Gross (2004/0253304) in view of Iddan (2003/0214580). Applicant respectfully traverses this rejection in view of the remarks that follow.

The Gross reference is directed primarily – as suggested by its title, “Active drug delivery in the gastrointestinal tract” – to drug delivery. The ingestible apparatus disclosed is intended solely for drug administration. The sole embodiment Applicant could locate in Gross’ 60-page disclosure is the one referred by the Examiner, i.e., at para. [0075]:

[0075] In some embodiments of the present invention, the functionality for activating the driving mechanism, described hereinabove as being provided by a coating, is supplemented or replaced by other activating functionalities. For some applications, the capsule comprises a bio-sensor that detects a biological or physiological parameter, and activates the driving mechanism responsive thereto. As appropriate, the bio-sensor may comprise one or more of the following: an enzymatic sensor, a temperature sensor, a pH sensor, or a timer (the timer typically comprising chemicals that react in a known manner to activate the driving mechanism at a predetermined time following an event such as the patient squeezing the capsule or the patient ingesting the capsule). Alternatively or additionally, the capsule comprises a camera, which records an image of the GI tract for on-board analysis and, if appropriate, activation of the driving mechanism in response to the image. (Gross para. [0075], emphasis added)

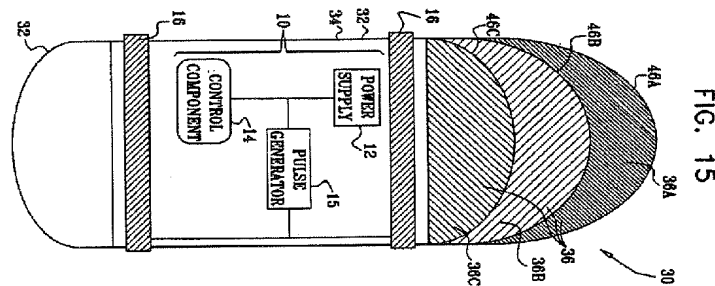
Thus, the embodiments associated with the camera embodiment have a driving mechanism for releasing the drug at a location determined by on-board analysis of an image acquired by the camera, or by transmission of the image and analysis by a physician. Such embodiments are depicted in Figs. 21-30, and in particular, at Fig. 30, reproduced below:

FIG. 30



However, in order to find a detachable appendage, the Examiner points to an entirely different – and incompatible – embodiment in the Gross reference, i.e., para. [0367] and Fig. 15:

[0367] For other applications, the pH value is selected to be in the range commonly found in the stomach, e.g., between about 1.2 and about 3.5, such that film 46A dissolves in the stomach, releasing at least a portion 36A of drug 36. Optionally, system 30 comprises a second film 46B, which dissolves at a pH characteristic of a more distal portion of the GI tract, such as the small intestine, releasing a second portion 36B of drug 36 therein. Further optionally, system 30 comprises a third film 46C, which dissolves at a pH characteristic of a still more distal portion of the GI tract, such as the large intestine (e.g., a pH value of between about 7.5 and about 8.0 for the large intestine), thereby releasing a third portion 36C of drug 36. In this manner, specific drug portions, or even different drugs 36A, 36B, and 36C may be targeted to different portions of the GI tract. Alternatively or additionally, the pH values are selected to release a first portion of drug 36 in the small intestine, and a second portion in the large intestine. (emphasis added)



Thus, in this embodiment, the drugs 46A, 46B, and 46C are released on a time-basis alone. There is no actuated driving mechanism (such as depicted in Fig. 21, etc.), and therefore, there is no need for a camera to capture images and determine the location to actuate the driving mechanism for drug release.

The Gross reference, therefore, does not disclose an ingestible device having both a camera and a detachable appendage. The mere fact of two entirely different embodiments in Gross – one having a camera and the other having a detachable appendage – is not prima facie evidence of obviousness, and in view of the disparity of the embodiments, this in fact teaches away from including both the camera and the detachable appendage in a single embodiment. Therefore, Gross does not disclose a device having these features, and it would not have been obvious to one of ordinary skill to combine a camera with a detachable appendage based on Gross.

Further, the Examiner concedes that Gross does not disclose a spherical housing to contain the imager, and cites the Iddan reference for disclosing interchangeability of the shapes of imaging capsules. However, the Examiner provides no motivation to one of ordinary skill to modify the Gross reference to make the capsule spherical. The Examiner evades this by stating that it would have been obvious “to construct the sheath of Gross in whatever shape is efficacious.” This is an improper prima facie obviousness rejection. The Supreme Court in KSR v. Teleflex held:

One of the ways in which a patent’s subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent’s claims.

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The Examiner has not pointed out what problem was known at the time of invention that a spherical imaging capsule would have solved, particularly in conjunction with the present claim, i.e., a detachable appendage forming an oblong shape together with the spherical capsule.

Claims 12-20 depend directly or indirectly from claim 11, and therefore include all the limitations of this claims. At least for this reason claims 12-20 are likewise allowable. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejections under 35 U.S.C. § 103(a) over Gross in view of Iddan, and allow all pending claims.

In addition, neither Gross nor Iddan discloses an ingestible device "wherein an imaging axis of said imaging device is aligned with the oblong axis of the detachable appendage when joined together," as recited in claim 35.

Finally, Applicant has newly added claims 36-46, relating to a method of in vivo imaging using the device of claim 11, that is neither disclosed nor obvious in view of the cited art. In particular, even if Gross were to disclose combining a camera with a detachable appendage, it does not disclose or render obvious continuing to image an in vivo segment after the detachable appendage has been detached. Thus, claim 36, which recites "imaging a first in vivo segment while the imaging device and the detachable appendage are joined; detaching the detachable appendage; and after detaching the detachable appendage, imaging a second in vivo segment," is allowable over Gross in view of Iddan.

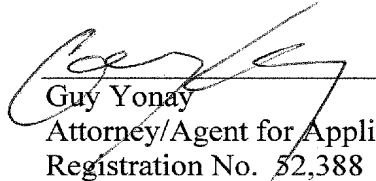
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In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,

  
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Dated: February 12, 2008

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